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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONVENTION NO.
09/592,032	06/12/2000	Flemming Junker	3500-244-US	5100

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Novo Nordisk of North America Inc  
Suite 6400  
405 Lexington Avenue  
New York, NY 10174-6401

EXAMINER

LIC, SAMUEL W

ART UNIT	PAPER NUMBER
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2653

DATE MAILED: 03/11/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/592,032

Applicant(s)

JUNKER ET AL.

Examiner

Samuel W Liu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on 09 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☐ Claim(s) 1-9, 11-18 and 20-27 is/are pending in the application.
- 4a) Of the above claim(s) 15-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-9, 11-14 and 20-27 is/are rejected.
- 7) ☐ Claim(s) 20 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on 12 June 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

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### **DTAILED ACTION**

The response filed 9 December 2002 (Paper No. 8) as to cancellation of claims 10 and 19, addition of new claims 20-27, and amendment of claims 1-3, 6-8, 11-13, 15 and 17-18 have been entered. The following Office action is applicable to the pending claims 1-9, 11-14 and 20-27. The drawing filed 12 June 200 have been approved by US PTO drafting.

Acknowledgment is made of applicant's claim for priority under 35 U.S.C. 119(a)-(d) based upon an application filed in declaration on 12 June 2000 ( the claimed foreign document Demark 1687/90, received on 9 December 2002). A claim for priority under 35 U.S.C. 119(a)-(d) cannot be based on said application, since the United States application was filed more than twelve months thereafter.

Note that the grounds of objection and/or rejection not explicitly stated and/or set forth below are withdrawn.

### ***Terminal Disclaimer***

The terminal disclaimer filed on 9 December 2002 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of Application No. 5780599 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Rejection under 35 U.S.C. 101, double patenting is withdrawn, and the claim rejection by obviousness type double patenting is also withdrawn because the terminal disclaimer applicants filed on December 9, 2002 overcomes an this provisional rejection based on a nonstatutory double patenting ground wherein the conflicting application or patent is shown to be commonly owned with this application.

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***Objection to Claims***

The disclosure is objected to because of the following informalities:

In claims 20-22, "v/v" is missing after the phrase "0.1 to 20%".

Appropriate correction is required.

***Object to IDS***

Please note that Applicants' submission of IDS filed 12 June 2000 is incomplete since it contains no legible copies of each U.S. and foreign patent and each publication or that portion which caused it to be listed as cited in the list of the submitted IDS. Thus, it fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C (1).

The response filed 9 December 2002 asserts that the copies of the references in the June 12, 2000 IDS could be found in a prior application 07961932. Please note that the current application has no copendency with Application 07961932 as evidenced by that neither in the disclosure nor in the declaration of the instant application applicants have claimed 07961932 is a copending application to the current application. Thus, applicants are invited to provide the IDS documents.

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***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite in the recitation of "...from about 0 to about 30 °C ...", because it is ambiguous as to what temperature for growing the claimed crystal encompassed in the limitations. The recitations appear to set a " $\pm$ " parameter on both ends of the °C temperature range permitting GH crystal growth. It therefore would result in a vague and unpredictable range for using claimed growth condition that is critical for uniformity, size, stability and yield of resultant crystal. The °C must be clearly defined since the temperature is one of most critical determinants for the crystal growth. See also claims 6, 14, 17 and 25.

Also, claim 1 is indefinite as to what are or are not "GH derivatives". See also claims 13 and 15. The dependent claims are also included in the rejection.

Claim 21 is indefinite as to the recitation "from 5 to 1%" because the range of the organic solvent that is added in the solution for the crystal growth is not consistent with the range set forth in the rest claims, e.g., claim 20 and 22.

*Response to the rejection under 35 USC 112, the second paragraph*

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The response filed 9 December 2002 asserts that the recitation of "from 0 to about 30 °C" is not indefinite as the same language was considered in an issued patent (see page 6, the second to the last paragraph). The applicant's argument is not persuasive because of the reasons set forth in the above rejection, and because the claims are examined toward the current application *per se*.

Also, the response argues about "derivative" in the claims because the recitation was also used in an issued patent (see page 6, *ibid*). The argument is unpersuasive because it is unclear whether or not the "derivative" refers to a genetic mutant of GH polypeptide, or a naturally-occurring splicing variant of GH, or a chemical modified GH molecule, or a fusion polypeptide of GH, and because has nowhere in the specification defined the derivative.

#### ***Claim Rejections - 35 USC §102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9, 11-14 and 20-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Junker, F. *et al.* (US Pat. No. 5780599). Note this rejection is based on the fact that the current application does not enjoy the status of the foreign document: Denmark 1687/90 (see also the foregoing statement). Thus, the filing date of the instant application is deemed to be 12 June 2000.

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Junker *et al.* teach a process of producing cation crystals of growth hormone (GH) (see the patent claim 1 and column 3, lines 31-42), comprising addition of organic solvent to a solution of GH at a pH 5.8 and 6.5 or 5.0 and 6.8 (see the patent claim 1 and column 2, lines 58-60), and isolating the produced cation crystal (see claim 1, step C). The Junker patent anticipates claim 1 of the instant application.

Junker patent also anticipate the claims 2, 3, 4, 5, 6, 7, 8-9, 11, 12, 13 and 14 of the current application; see the patent claims 11, 2, 3, 4, 5, 6-8, 13, 14, 15-17, 10 and 12, respectively.

Further, Junker patent anticipate the claims 20, 21, 22, 23, 24, 25, 26 and 27 of the current application; see the patent claims 7, 8, 9, 16, 17, 22, 22 and 11.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is (703) 306-3483. The examiner can normally be reached from 9:00 a.m. to 5:30 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low, can be reached on 703-308-2923. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4242 or 703 872-9306 (official) or 703 872-9307 (after final). Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 305-4700.

Samuel Wei Liu, Ph.D.  
March 7, 2003

*Samuel Wei Liu (to be signed)*

KAREN COCHRANE CARLSON, PH.D.  
PRIMARY EXAMINER